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ABSTRACT
The focus of this summary volume reporting on several parallel studies is an application of technology to the problems of health care and the role of the university in responding to health care needs through biomedical engineering. A brief description of the National Academy of Engineering (NAE) is presented. A list of reports, issued by the Committee on the Interplay of Engineering with Biology and Medicine (CIEBM) and available from NAE, is presented as well as a list of Committee, Subcommittee, and Task Group Members (1967-1973). (Author/EB)

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Committee on the Interplay of Engineering with Biology and Medicine

NATIONAL ACADEMY OF ENGINEERING

Study of Engineering in Medicine and Health Care

Committee on the
Interplay of Engineering with
Biology and Medicine

Study of Engineering in Medicine and Health Care

A final report to the
National Institutes of Health

NATIONAL ACADEMY OF ENGINEERING
WASHINGTON, D.C. 1974

Subcommittee on Sensory Aids
ROBERT W. MANN, *Chairman*
Subcommittee on Interaction with Industry
MURRAY EDEN and SAUL PADWO, *Co-Chairmen*
Subcommittee on Engineering in Clinical Care
RICHARD EGDAHL and CESAR CACERES, *Co-Chairmen*
Subcommittee on Technology and Systems Transfer
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Task Group on Industrial Activity
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NATIONAL ACADEMY OF ENGINEERING

The National Academy of Engineering was established in December 1964. The Academy is independent and autonomous in its organization and election of members and shares in the responsibility given the National Academy of Sciences under its congressional act of incorporation to advise the federal government, upon request, in all areas of science and engineering.

The National Academy of Engineering, aware of its responsibilities to the government, the engineering community, and the nation as a whole, is pledged:

1. To provide means of assessing the constantly changing needs of the nation and the technical resources that can and should be applied to them, to sponsor programs aimed at meeting these needs, and to encourage such engineering research as may be advisable in the national interest;
2. To explore means of promoting cooperation in engineering in the United States and abroad, with a view to securing concentration on problems significant to society and encouraging research and development aimed at meeting them;
3. To advise the Congress and the executive branch of the government, whenever called upon by any department or agency thereof, on matters of national import pertinent to engineering;
4. To cooperate with the National Academy of Sciences on matters involving both science and engineering;
5. To serve the nation in other respects in connection with significant problems in engineering and technology; and
6. To recognize in an appropriate manner outstanding contributions to the nation by leading engineers.

Preface

The National Academy of Engineering in its role as an advisor to Congress and federal agencies has placed responsibility for studies of the engineering–medicine interface within its Committee on the Interplay of Engineering with Biology and Medicine (CIEBM). CIEBM was established in 1967 under an initial contract with the National Institutes of Health (NIH) to provide advice on the role of engineering in the development of medical and biological systems. The committee has since also undertaken a major study for the National Aeronautics and Space Administration (NASA) to aid the space agency in their efforts to apply NASA technology to health care delivery. The NIH study was completed on December 31, 1972; the NASA study was completed on June 30, 1973.

In the NIH study reported herein, the committee examined the basic developmental problems of bioengineering and socioeconomic limitations imposed on its growth and the constraints resulting from the artificial separation of engineering from biomedical fields in the nation's universities. The contract with NIH called for the Academy to investigate:

The role and extension of engineering concepts and technology in the scientific inquiry into biological phenomena as a basis for advancing the understanding of biological systems.

The utilization of engineering concepts and technology in the development of instrumentation, materials, diagnostic and therapeutic devices, artificial organs and other constructs relevant to the solution of major problems in the areas of biology and medicine.

The application of engineering concepts and theory to the development and further evolution of social systems and such microrepresentations of social systems as hospitals or related health service units.

The committee chose to follow two parallel paths. In one direction, the committee has sponsored a series of conferences to examine goals, limitations, and progress in applying technology to the problems of health care. Subcommittees were formed to consider such specific aspects of the field as technology transfer, sensory aids, clinical engineering, and government interaction with industry.

In the second direction, the committee subcontracted to a group of six universities to study ways in which they could respond to health care needs through biomedical engineering. The universities prepared prototype organization plans for coordinating university activities in bioengineering with those of local industries, communities, and the health care delivery system. This phase was completed in late 1968, and a report summarizing the results (*Prototype University Plans for the Development of Biomedical Engineering*) was published in April 1969.

These efforts were expanded in a second phase. Under new subcontracts with the Academy, three universities were followed during the initial implementation of their plans. This permitted an assessment of the means by which effective relationships among industry, the community, and the university could be established to optimize the solutions of urgent problems in medicine and health care.

At the request of NIH, other areas were investigated on an *ad hoc* basis; thus contained in this final report are the summaries of a study of biomedical engineering in foreign countries and an appraisal of needs in biomaterials research and development.

The bulk of work of the committee was carried out by its subcommittees and the Task Group on Industrial Activity to which the Academy and the Committee are deeply indepted. Without their diligent effort our task would not have been completed. We very much appreciate their contributions.

The work of the committee and subcommittees has also been greatly assisted by the CIEBM staff. The creative talent of Gilbert Devey, our first Executive Secretary, was instrumental in formulating and implementing the initial committee activities. His chair was ably

filled from October 1969, to September 1973 by Charles W. Garrett. Other staff members during the course of the study included Lonnie C. Von Renner (Professional Assistant), Abraham Leventhal (Professional Assistant), Ms. Jean Ruffin (Research Associate), Ms. Dorothy Campbell (Administrative Assistant), Ms. Marianna Shepard (Administrative Secretary), Ms. Ernestine Pierce (Secretary), Ms. Mary Alice McDonough (Secretary), and Ms. Mary Gordon (Secretary). Their efforts are most gratefully acknowledged.

W. ROBERT MARSHALL, *Chairman*
Committee on the Interplay of Engineering with Biology and Medicine

Contents

Introduction

. . . [B] iology and engineering are now developing–indeed have developed–a very broad interface; that this is producing close and productive contact between diverse biologists and engineers; and that proper exploitation through suitable coupling mechanisms will have profound effects on

- our understanding of disease,
- our ability to modify the consequences of disease,
- our understanding of many life processes and their control,
- our capacity for more precise diagnosis and treatment,
- our ability to manage our hospitals, and finally,
- our ability to develop more rational systems of patient care.*

Based on these assumptions, the Committee on the Interplay of Engineering with Biology and Medicine (CIEBM), under contract to the National Institutes of Health, was formed primarily to investigate and study "proper exploitation through suitable coupling mechanisms." From this, major emphasis was placed on studying how the university can serve as a focus for integrating the academic, industrial, and health care sectors of a community. Recognizing the leading part industry

*James A. Shannon, Director of NIH, presented at *Medicine, Biomedical Sciences, and Engineering*, Third Annual Meeting of the American Institute of Aeronautics and Astronautics, Boston, December 1, 1966.

plays in properly exploiting technology in health care, the committee also examined the factors that appear to enhance and inhibit industrial participation.*

Although the committee holds to Dr. Shannon's original contention as cited, many constraints impede the fulfillment of his hopes. Several major institutional barriers were revealed during the course of our study. These constraints, reducible only to the extent that the institutions that create them are capable of change, are discussed throughout this report.

The Health Care System—Placing Technology in Perspective

The major thrust of the committee's effort was to examine engineering applied to health care. Thus it is important to hold some appreciation for the problems inherent in the provision of health care in this country. That the nation faces a health care delivery problem has been well documented in the professional literature and the popular media. The President has spoken of the impending "massive crisis"; the Congress has devoted much study on federal programs to deal with it.

Cost statistics certainly do not describe in totality the nature of the problem. Nevertheless, they can aid in developing a qualitative insight. Consider, for example, the following:

1. Collectively, the national expenditure for health services is over $80 billion annually, an increase of over a factor of 5 in the last 20 years. Yet large portions of our population still do not receive adequate care, particularly those in rural or poverty situations.
2. The cost of medical care is skyrocketing. Daily hospital expenses have risen from about $40, 8 years ago, to $100 today. Yet one sixth of our population does not even have minimum insurance protection.
3. In the past 20 years, $20 billion have been expended on health-related research and development, and yearly expenditures per person for private health services have more than doubled in the same period of time. Yet life expectancy and, except for a very few selected diseases, patterns of morbidity have remained essentially unchanged. (The dramatic changes in these parameters occurred during the first 50 years of this century.)

Many reasons have been hypothesized for the problems in the health

*These and other studies in selected specific areas are reported in the many publications of the committee (Appendix A) and are summarized herein.

care system. The mechanism of health care delivery has been characterized as a "cottage industry"—a conglomeration of individual and independent practitioners, hospitals, clinics, laboratories, governmental units, etc., whose efficiency and quality have not been optimized, in part because of their very independence. A major characteristic of the system is a lack of obvious financial incentives for the institutions involved that provide care; they are almost solely nonprofit, and the overwhelming bulk of the cost of care is provided by third parties (i.e., insurance carriers and the government). Because of this situation and the very nature of the service provided (health care), the consumer also has little opportunity to evaluate cost benefits or alternative sources even if he had a sound basis on which to decide (which he does not).

Those responsible for leading the national attack on these problems are agreed on the following goals:

1. The quality of health care must be improved.
2. The quantity of health care must be extended and made more readily accessible to provide adequately for the needs of all citizens.
3. The mechanisms of financing health care must be altered.

In pursuing these targets, a vital question addressed by the CIEBM was, "How can technology contribute to their achievement?" That engineering should have considerable to offer is apparent. However, it is also important to realize that, as with all of the massive problems facing our society today, *technology and engineering alone cannot provide a solution to the improvement of health care.* Social, political, economic, legal, and moral factors are vital and dominant considerations. Nontechnical decisions and changes in national policies (for the most part beyond the purview of NIH) will greatly affect the degree to which technology can contribute; in fact, certain changes must occur (e.g., the construction of a more rational means of financing the costs of care) before the ultimate harvest of technological applications will be reaped.

Bioengineering and Biomedical Engineering

The terms "bioengineering" and "biomedical engineering" lack precise definition. Some proponents assume the broadest view and hold that bioengineering is the application of engineering principles and concepts to any endeavor or system that involves or affects living systems. (Under such a scheme, environmental engineering becomes a subset of

bioengineering.) Others hold a more limited view and demand that the bioengineer must be involved in applying his expertise directly on the living system to merit the name. Like views can be voiced for biomedical engineering as well. And recently the term "clinical engineering" has come into vogue to delineate the branch of the field that is closely coupled to the diagnostic and therapeutic practices of the health care delivery system.

Nevertheless, engineering has been a part of the attack on current problems involving living systems. Engineers are involved at the forefront of medical and biological research, mathematically modeling physiological systems and applying the principles of engineering to better understand, for example, the hydrodynamics of the cardiovascular system. Some are developing highly sophisticated and unique instruments required by research projects. On the other hand, there are those involved in the delivery system, some helping to analyze the operations of a hospital, others involved in the selection, maintenance and calibration of the instruments and devices in clinical use, others working within industry designing, developing, marketing, and modifying instruments and devices. And there are those in the university sphere, some dedicated to training other engineers, others working in areas such as the design and development of prosthetic devices. Within governmental bodies, engineers are working within the organizational elements that attempt to coordinate and direct the resources of a nation, a state, a city, to provide health care.

Summary of Activities

Key Characteristics

The field of biomedical engineering has certain key characteristics that differentiate it from many of the more traditional engineering disciplines (e.g., civil or mechanical engineering). These are set down to add some overall perspective to the summary of specific CIEBM activities that follows.

1. Although engineers have applied themselves to problems in medicine and health care for many years, the field has received recognition as a distinct branch of engineering only relatively recently. The leaders of the field that exist today are, for the most part, the first generation of such leadership.

2. As a distinct group in comparison with other major engineering areas, biomedical engineers represent a small number of people. The amorphous definition of a biomedical engineer, coupled with the variety of sectors in which he may be employed (hospitals, industries, government agencies, and other health care delivery institutions), makes it difficult to estimate with any degree of precision the size of the field. One recent report* estimates (within a factor of 2) that only approxi-

*"The Future of Training in Biomedical Engineering," *IEEE Trans. Biomed. Eng.* 19:148-155 (1972).

mately 6,000 engineers are currently employed full time in the field.

3. The growth of the field in the past 10 years has been stimulated and led by the university sector.* Until very recently, the emphasis has been on applying engineering science and talent to challenging research problems in medicine and biology. The focus has been in doctoral programs of universities. Thus, for example, the only organized federal support of education in the field has been a program providing training grants and fellowships for Ph.D. candidates. Within the past year or two, greater attention has been given to the need for engineers of lower academic achievement to supply industry and health care delivery institutions. However, this attention has been primarily limited to voicing the need for and philosophical explorations of appropriate roles of engineers. A concerted national effort to provide the people and engineering services required remains to be mounted.

4. To date, it has been primarily the biomedical engineering community itself that has recognized its need and value in health care delivery. While the health care delivery system begs for more physicians, nurses, physician assistants, and other allied health personnel, one does not often hear the system cry for biomedical engineers. Thus, while the biomedical engineer recognizes the contributions that he can make to health care delivery, the delivery system does not appreciate this need; therefore, the market for biomedical engineers and their services is still quite limited.

5. Bioengineering in all its contexts is a multidisciplinary field involving fundamental engineering and the fields of biology, economics, sociology, psychology, and medicine. Biomedical engineers rarely operate in solo practice. Each is directly and intimately involved in a relationship with others in the life, social, and physical sciences as well as with the medical profession. Thus, the role of the engineer operating in medicine and biology often goes beyond purely technical matters.

6. At the federal government level, there is no identified central agency with the prime interest or responsibility in the field of biomedical engineering for health care delivery. Although the Health Services and Mental Health Administration† may be assumed to have the prime government responsibility for health care delivery systems, primary government support for biomedical engineering has come from the National Institutes of Health; in particular, the training programs of the National Institute of General Medical Sciences. There is very little coordination between these two agencies and others (Veterans' Ad-

*In contrast, most mature engineering disciplines are most heavily influenced by industry.
†Now abolished.

ministration, Department of Defense, Atomic Energy Commission, National Aeronautics and Space Administration), all of which have biomedical engineering programs of some magnitude.

Conclusions and Recommendations

The conclusions and recommendations of the specific CIEBM activities are quite extensive and will not be summarized here. Instead a listing is provided referencing the pages in the report on which conclusions, recommendations, or similar matters are stated.

Phase I: University Prototype Studies

Background

Task Order No. 39 with the National Institutes of Health required the committee to examine in detail, through subcontracts or other appropriate arrangements, at least three institutional involvements in biomedical engineering and to develop appropriate institutional prototypes for the further advancement of the relationship among biology, medicine, and engineering. In meeting this requirement, the committee awarded subcontracts to six universities to:

1. Develop concepts for relating university activities in engineering to the physical, biological, medical, social, and management sciences. The goal was to secure the most effective interplay of these fields in advancing medical and biological research, to find practical solutions to urgent problems in medicine and health care, and to stimulate the training of professional people to work effectively in this multidisciplinary endeavor.
2. Identify and assess particular industrial and civic resources that can contribute toward solution of the problem and to study the operations of health and medical care institutions and focus on issues that can be resolved through collaboration of medicine and engineering.

3. Develop prototype operational plans to secure the most effective relationship among elements of industry, the community, and the university that will stimulate research and obtain the best combination of resources for dealing with vital medical and health care needs.

The subcontracts were awarded in response to requests for proposal sent to 52 institutions. Twenty-nine formal proposals were received. An evaluation subpanel of the committee reviewed the submissions and recommended the award of subcontracts to six universities: Harvard University and the Massachusetts Institute of Technology acting as one team, The Johns Hopkins University, University of Washington, University of Virginia, Carnegie-Mellon University, and The Ohio State University. Several other universities indicated that planning already under way would continue in parallel with those subcontractors. The six were chosen not only for the quality of their proposals but also because of basic differences in their environment. Thus, for example, the Harvard-MIT combine was characterized by a pair of institutions, one strong in medicine and the other in engineering, located within a large eastern metropolitan area containing extensive industrial and medical elements. The University of Virginia, on the other hand, is remote from large industrial centers. Ohio State is in the midst of a large commercial and industrial area (on the order of 8,000 sq mi) with strong industrial and research resources adjacent to a major university with complete engineering and life science facilities. Ohio State's biomedical engineering program, typical of most, had its birth in the engineering school (in particular, within the Department of Electrical Engineering) and grew in an interdisciplinary fashion to include seven colleges and twenty departments. In contrast, while similarly situated in a large industrial region, the Johns Hopkins program was developed within the medical school. Carnegie-Mellon faced the unusual challenge of having no medical school; it had to develop ties to local hospitals and other institutions to provide the necessary health care resources and facilities for its program.

Thus the six sites were quite different in nature. It is not surprising, therefore, that the six plans, while sharing some common elements, also had some features unique to each.

The six subcontracts were awarded in March 1968. Work proceeded according to schedule and final reports from each university for this Phase I (the planning phase) of the university prototype study were received in October of the same year. In addition to careful examination of the reports, CIEBM conducted site visits to each institution and held a concluding conference at which each plan was critically reviewed.

Results

The committee summary of the six plans* classified them into three broad categories: (1) university prototype plans, (2) joint university-community-industry prototype plans, and (3) integrating and coordinating programs.

University Prototype Plans

The committee identified eight issues and questions that require serious attention if engineering is to fulfill its potential in contributing to the solution of national health problems (Table 1). The extent to which each university's prototype plans relate to these stated needs is indicated in the table.

All but one of the universities proposed intrauniversity programs for adapting traditional interdisciplinary programs for education and research in biomedical engineering. The organization for the programs consisted of a multidisciplinary faculty committee representing engineering, biology, and medicine to plan curricula, research, and degree criteria.

Joint University-Community-Industry Prototype Plans

The proposals for community, health care, and industry interaction were extensive and varied in all cases. Each, however, stressed the need to involve the universities in direct collaboration with the outside community. Issues common to all included:

1. Plans to establish and develop new university-community organizations to coordinate and integrate university resources for application to the problems of health care units, industry, and government groups.
2. Plans to develop appropriate positions and faculty opportunities to attract traditionally oriented academic staff to the challenges of mission-oriented programs involving engineering, medicine, and society. This problem was generally referred to as "faculty motivation."
3. Expectation that priming funds would probably come initially from federal sources, with the anticipation that other sources in the community and in industry would respond in time.

**Prototype University Plans for the Development of Biomedical Engineering,* National Academy of Engineering, Washington, D.C. (April 1969).

TABLE 1 Topical Statements and Questions

1. **The medical community has been slow to recognize, accept, and apply the advances of modern technology. How can this attitude be improved?**

   Carnegie-Mellon: A plan is proposed to establish a Center for Technological Innovation in Health Care to bring new technology more rapidly to hospitals and health care units.

   Harvard-MIT: A new organizational structure is proposed for matching the interests of researchers to facilitate collaboration.

   Johns Hopkins: The technique of special seminars will be used as in the past to bring engineering and technology to bear on medical problems described by doctors.

   Ohio State University: The formation of the Central Ohio Biomedical Engineering Community Council (COBECC) is expected to bring together medical and engineering practitioners.

   University of Virginia: A systems approach with control centers is proposed to accelerate the introduction of engineering into medicine.

   University of Washington: An advisory board including representatives from five leading hospitals and six local industries will attempt commercial solutions to medical problems.

2. **Training programs are required that can (a) produce bioengineers well qualified to work in the biomedical context and (b) provide medical and biological specialties with appropriate training in the physical and engineering sciences. What is the state of the programs that now exist, and how should they be modified?**

   Carnegie-Mellon: No special educational programs relevant to this need were reported.

   Harvard-MIT: The new organizational facility will encourage experimental educational programs to educate (1) bioengineers and (2) the biologist and physician in physical sciences and engineering.

   Johns Hopkins: A graduate program in biomedical engineering jointly sponsored by engineering and medicine fulfills topic 1, and courses offered by a subdepartment on biomedical engineering in the regular medical curriculum partially meets topic 2.

   Ohio State University: The biomedical engineering program at Ohio State is to be strengthened by (a) educational opportunities for engineers in the life sciences, (b) a biomedical engineering graduate program with life science laboratory experience, and (c) introduction of a premedical curricula in engineering.

   University of Virginia: The University of Virginia has an active graduate program offering the D.Sc. in biomedical engineering awarded by the School of Engineering and Applied Science.

   University of Washington: Broadly based educational programs involving seven engineering departments and several departments from the schools of medicine, dentistry, and nursing were proposed to provide biomedical education for engineers and doctors.

TABLE 1 (continued)

3. Industry has been slow to produce, at reasonable cost, effective and reliable components, devices, and systems necessary for modern research and health care. How can this situation be bettered?

Carnegie-Mellon: This problem is to be attacked through the Center for Technological Innovation in Health Care.

Harvard-MIT: The new organization will encourage development programs on biomedical products and systems.

Johns Hopkins: A proposed Health Care Research and Development Center would be expected to contribute to the solution of this problem.

Ohio State University: COBECC is intended to meet this need through stimulation of interaction between industry and the health care market.

University of Virginia: A specific systems approach would be applied to each identified need in health care, hospital operation, etc. A control center would be appointed for each system.

University of Washington: The advisory board of university, hospital, and industrial representatives is concerned with this problem.

4. The costs of health care are increasing dramatically while in most other areas the trends toward increased costs have been countered with new technological developments. What can be done to reduce costs of health care?

Carnegie-Mellon: Two methods were suggested: (a) hospital cooperative plan between CMU and West Penn Hospital; (b) Center for Technological Innovation in Health Care.

Harvard-MIT: Management, science, and engineering will be applied to improving medical care. Research to be conducted on a fairly large urban population.

Johns Hopkins: The proposed center has this problem as one of its objectives for solution.

Ohio State University: A prime objective is to cope with various problems of health care and to identify necessary capabilities for solving the problems through COBECC and the university biomedical program.

University of Virginia: A proposed Biomedical Communications Center could contribute to solving this problem, along with the proposed systems and control centers.

University of Washington: The divisions of bioinstrumentation and clinical engineering are oriented toward health care problems.

5. Engineers lack the recognition, status, and opportunities required to be effective collaborators with medical professionals. What can be done to meet these needs?

Carnegie-Mellon: No specific plans were proposed.

Harvard-MIT: No plans were reported.

Johns Hopkins: The report noted this problem and believed it was solved at Johns Hopkins.

TABLE 1 (continued)

Ohio State University: The university program and COBECC are designed to provide an operational recognition of engineering professionals.

University of Virginia: The control center plan and demonstration programs are designed to meet this need.

University of Washington: The engineering and life sciences facilities are working as equal partners on problems of mutual interest.

6. **The developments from engineering research and education must be communicated to the medical community and to industry if their full value is to be realized. What are some imaginative and practical methods for doing this?**

Carnegie-Mellon: The Center for Technological Innovation in Health Care will provide information service.

Harvard-MIT: A new organization will be established to provide information service to medical centers and industry.

Johns Hopkins: The proposed Health Care Research and Development Center will presumably meet this need.

Ohio State University: This problem will presumably be a concern of COBECC and the interdisciplinary university program.

University of Virginia: The proposed systems and control centers would contribute to solving this problem.

University of Washington: Cooperative relationships through personal contact with many off-campus organizations have been established to develop bioengineering as a community resource.

7. **The universities must innovate and improve methods for incorporating relevant medical and biological training for engineers into the total educational program. What steps are being taken in this connection?**

Carnegie-Mellon: The biotechnology program provides interdisciplinary biomedical educational opportunities.

Harvard-MIT: Experimental education programs were proposed for biomedical engineering.

Johns Hopkins: The subdepartment on biomedical engineering will encourage the teaching of engineering to medical students for application to medical practice.

Ohio State University: A plan is proposed to introduce engineering concepts into life science and medical curricula by developing special courses and to introduce premed and life science courses in engineering programs.

University of Virginia: A training program for biomedical electronics technicians is proposed.

University of Washington: This is being accomplished by numerous joint programs in areas such as ocean engineering, the health services research center, and the aerospace program.

TABLE 1 (continued)

8. Career opportunities for engineers in medicine and biology must be identified and made known to students. What are the identifiable career paths and rewards?

Carnegie-Mellon: No specific plan or study was reported.

Harvard-MIT: No plans or studies were reported.

Johns Hopkins: No plans or studies were reported.

Ohio State University: No plans or studies were reported.

University of Virginia: Although no plans or studies were reported, some statistics were reported on positions in hospitals.

University of Washington: Career opportunities are being explored through the affiliation with local industry in an effort to provide job positions for graduates of the bioengineering program.

Integrating and Coordinating Programs

Plans for the proposed coordinating groups were, for the most part, in preliminary stages. Implementation was expected in 1969 or later. The principal requisite for implementation was judged to be properly trained personnel.

Phase II: University Prototype Studies

Background

Out of the Phase I planning effort grew a follow-on activity of the committee. Three universities were chosen as candidates for a study of plan implementation. Subcontracts were awarded in February 1969, to The Ohio State University, The Johns Hopkins University, and the University of Wisconsin. The general objective was to document, while the prototype plans were put into practice, the progress made toward establishing an effective relationship between industry, the community, and the universities to advance research efforts and to seek optimum resources for solving urgent problems in the medical and health care areas. The Ohio State and Johns Hopkins efforts were natural extensions of the CIEBM's Phase I programs. The University of Wisconsin had conducted its planning independent of NAE support and was well prepared to proceed on the Phase II effort.

Each university was asked to provide recommendations on the following issues:

1. The current conditions of industrial interaction in the biomedical engineering field;
2. The problems connected with involving industry in the field's development;

3. Unique opportunities for the resolution of these problems;
4. Obstructions to the realization of these opportunities; and
5. The educational and training needs and problems in multidisciplinary development programs for biomedical engineering.

Results

As with the Phase I effort, the committee remained apprised of subcontractor activity by means of site visits, oral progress reports at CIEBM meetings, and frequent correspondence. In February 1970, a workshop was held in which the three Phase II universities, together with the four other Phase I institutions, presented oral and written summaries of progress made toward plan implementation. A synopsis of the major features of each as of that time is given in Table 2.

The Johns Hopkins University

Both Johns Hopkins and Wisconsin focused on strengthening and broadening their university-based biomedical engineering programs. Johns Hopkins established an "Office of Health Care Programs" and, within it, a "Health Services Research and Development Center." Projects were initiated supporting the establishment of two Hopkins-operated prepaid health care programs: (1) intrauniversity medical research and patient care (e.g., medical records, automated history taker) developments and (2) collaboration with industry in the early stages of development and in the evaluation of prototype devices and systems. A second major commitment of Hopkins in Phase II was to curriculum development in both the medical school and in biomedical engineering; the latter was accorded full department status during the course of the subcontract.

A complete summary of the Johns Hopkins effort is contained in their report to the committee.*

University of Wisconsin

At the University of Wisconsin, the establishment of a "Biomedical Engineering Center" was approved with a broad list of functional responsibilities to meet educational and research needs of the university and to satisfy needs perceived in both the industrial and the health care de-

*Johns, Richard J., *Report on the Interplay of Engineering with Biology and Medicine*, Johns Hopkins University, Baltimore, Maryland (August 1970).

TABLE 2 University Biomedical Engineering Programs[a]

The Ohio State University

Focus: Program is university-initiated, but both community- and university-centered. Membership is regionwide and includes multi-interest groups.

Organization: University Coordinating Committee on Biomedical Engineering represents the involved departments under Vice President for Academic Affairs. Extrauniversity community Council (COBECC). Administrative committee of six (three life science, three engineering) serve as board of directors. Project review board advises on technical activities. Seven interest groups serve as forums for discussion of problems in depth.

Research Interests: Important emphasis on computer technology for hospitals and health care; major research efforts are mission-oriented in instrumentation, systems, aids for speech impaired, vision, prosthetics, basic physiology. Some basic research.

Recommendations: (1) Better collaboration with industry for university-centered R&D on common projects; (2) training of biomedical technicians with emphasis on operation, service, and use of modern biomedical instrumentation; (3) community education in state of the art problems and needs of both engineers and life scientists; (4) degree programs with suitable emphasis on alternate subjects for both engineers and life scientists.

Activities: COBECC membership now over 300; seven interest groups meet monthly, organize workshops to encourage exchange and dissemination of information among the community, industry, and university. University program contains over 100 undergraduate and graduate students; over 40 interdisciplinary research and development projects; B.S., M.S., Ph D., premed, and combined programs.

Relations with Industry: Direct interaction among COBECC, industry, and university. General survey conducted of over 800 industries in Columbus area to determine interests, capabilities, and problems in biomedical engineering field and to identify local available skills and resources. Should be greater communication between academic and industrial communities. Industry should be convinced of profit to be found in biomedical field.

University of Wisconsin

Focus: Program is faculty-initiated and university-centered and acts mainly in liaison capacity as forum for exchange of information and coordination of campus research.

Organization: Coordinating Committee on Bio-Engineering (CCB) composed of 19 senior faculty members from engineering and life sciences. Coordinates research activities and organizes workshops and symposia.

Research Interests: Most research projects are mission-oriented; concerned with development of devices and measuring techniques for patient care and instrumentation to improve diagnostic techniques. Very little emphasis on computer technology and systems approach to health care.

Recommendations: (1) Closer research collaboration with industry; (2) centers

TABLE 2 (continued)

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to provide engineering expertise to medical community as regards research and hardware selection, procurement, maintenance, and calibration. (3) Standardization programs; (4) regional centers for better health care delivery; (5) implementation and expansion of education programs with less emphasis on Ph.D.

Activities: Programs concerned mainly with (1) university/industry development projects; (2) standards for medical instrumentation and measurements; (3) engineering and industry in hospital planning; (4) biomedical engineering training and education. Suggested formation of regional centers.

Relations with Industry: Conception of engineering data package. Discussions with 14 selected companies: reticence to biomedical engineering products due to difficulty in stimulating market potential; reservation in acceptance of medical community; industry does not need doctoral level bioengineers and scientists but rather master's degree with medical science orientation.

The Johns Hopkins University

Focus: Program initiated in faculty of medicine, is university-centered, and university- and hospital-administered. Main concern is health care.

Organization: University-wide committee of 21 senior faculty members advises on biomedical engineering programs both with regard to collaborative research and education. Interest mainly university centered, i.e., health care and education.

Research Interests: (1) Medical records automated system; (2) cardiovascular physiology; (3) ballistocardiography; (4) radiology instrumentation; (5) multiphasic screening; (6) programming for primary patient care.

Recommendations: (1) Complementary transition programs for engineering needing more life science knowledge; (2) courses at undergraduate level in both fields; (3) special skills courses; (4) development of postdoctoral programs with bioengineering orientation; (5) need for greater collaboration in research; (6) greater collaboration with industry.

Activities: Office of Health Care Programs (including Health Services R&D Center) established: (1) application of technology to oncology and diabetic management; (2) reorganization of computer-based medical records system; (3) implementation of computer-based appointment system.

Relations with Industry: Traditionally, has remained aloof from industrial consultation. Now recognizes importance of this and has begun active cooperation in projects including use of computers for automated history-taking and drug-ordering, cardiovascular assist and by-pass devices, and a systems analysis study of military hospitals.

Carnegie–Mellon University

Focus: Program is technologically oriented and university-centered. Absence of school of medicine presents drawbacks. Main interest is statewide health care.

Organization: Steering committee formed, with part-time services of three prominent Pittsburgh physicians to act as co-directors of health care project. Full-time senior fellow acts as project coordinator.

TABLE 2 (continued)

Research Interests: (1) Thoracic impedance monitoring; (2) connective membrane oxygenators; (3) modeling brain mechanisms; (4) measurement of oxygen exchange of hemoglobin; (5) optimal coding for spelled speech reading aid; (6) information processing; (7) heart valves; (8) electron microscopic studies of structure of biomaterials.

Recommendations: (1) Extension of surveys to determine health care needs and priorities throughout the state; (2) greater exchange of information with industry; (3) greater exchange of information between academic and medical communities on problems of mutual interest.

Activities: Center for W. Pennsylvania Health Services R&D. First of proposed statewide network of four or five similar centers. Broad objective: collaboration among university, medical, and industrial communities for improvement of health care.

Relations with Industry: Probing for industrial outlets.

University of Washington

Focus: Strong collaborative spirit between engineering and life sciences. Main interest in interdisciplinary research and development; faculty-oriented and university-centered.

Organization: Core staff comprises a director, assistant director, and two program coordinators with six research divisions: biomechanics and biomaterials, sensory engineering, analytic biology, instrument development, clinical engineering, and health care research. These divisions are based on a broad spectrum of collaborative research projects.

Research Interests: Intramural multidisciplinary projects in anesthesiology, artificial kidney, cardiovascular center, health service research center, aerospace science, aerodynamics, fertility control, ocean engineering, physical medical rehabilitation, applied physics. Most faculty projects are mission-oriented.

Recommendations: (1) Closer ties with industry; (2) implementation of graduate training for engineers in the life sciences; (3) active effort to establish communication and cooperation between the university and the community in areas of mutual interest; (4) greater need for interdisciplinary team projects.

Activities: Initial thrust of bioengineering program to foster strong collaborative research. Close affiliation with Battelle Seattle Research Center and Battelle Pacific Northwest Laboratories in Richland for commercial development of instrumentation. Promotion of courses for greater interaction between engineering and life sciences.

Relations with Industry: Active efforts made to excite interest of local industrial leaders produced transient but largely unsustained responses. Nonetheless, several development projects have been started on a collaborative basis. Battelle Development Corp. for survey of patent and marketing possibilities.

University of Virginia

Focus: Program faculty-initiated but community-oriented. Main interest is health care technology. Control center is university-administered.

TABLE 2 (continued)

Organization: Control center staff comprised of faculty members with major interests to promote medical technology in the community and to improve the delivery of health care. Further control centers are being planned.

Research Interests: (1) Systems approach to health care; (2) development of prototype intensive care unit; (3) prosthetic urethral valve; (4) heart and temperature monitoring devices in newborns; (5) preprocessors for recording physiological data.

Recommendations: (1) Better measurement techniques; (2) better understanding of biological function prerequisite for development of most suitable technological and socioeconomic systems; (3) expansion of exchange program of staff and students with foreign universities; (4) formal organization of biomedical engineering communication center.

Activities: Application Engineering Center to improve utilization and transfer of technology to biomedicine. Development of Prototype Intensive Care Unit. Implementation and expansion of education program and introduction of training in systems concepts (in cooperation with Langley Research Center).

Relations with Industry: Systems Control Center formed; funded jointly by the university, NASA, and industry. Appreciate importance of industrial cooperation, but program only in early stages of investigation.

Harvard-MIT

Focus: Interinstitutional committee; emphasis mainly on education and research programs. Interfaculty-administered and university-centered.

Organization: Steering committee, interinstitutional, comprising 16 task groups.

Research Interests: Most projects are mission-oriented. Some basic research and systems analysis and automated systems.

Recommendations: None offered.

Activities: Currently seeking to resolve differences in institutional arrangements. Proposed projects include development of educational programs at undergraduate, graduate, and postdoctoral levels; establish new knowledge in biomedical engineering to health care.

Relations with Industry: Both universities already have many ongoing projects in collaboration with industry.

[a]Status as of 1970.

livery sectors in the state. Based on the results of field interviews, a major focus of the Wisconsin project revolved around a concept of providing advisory engineering services to physicians, clinics, hospitals, and other components of the health care delivery system faced with selecting, procuring, calibrating, and maintaining instruments and devices. This emphasis was coupled with a study of instrumentation and measurement standards and also included the ways in which the center could benefit Wisconsin's biomedical device and instrument industry.

Additionally, during the subcontract period, greater faculty involvement in biomedical engineering programs was achieved; symposia, seminars, and continuing short courses were held; curriculum development occurred; and impediments to the medical acceptance of technology were studied. The details of the entire effort are contained in the university's three-volume final report.*

The Ohio State University

Implementation of Phase II at Ohio State (OSU) also involved the development of university programs in biomedical engineering. It resulted initially in an informal recognition by the Academic Council of the Interdisciplinary Bio-Medical Engineering Program, cutting across the colleges. Ultimately, the OSU Bio-Medical Engineering Center was formed, which included seven colleges and twenty departments. Additionally, and uniquely, it also included the formation of a novel organization based *outside* of, but interfaced with, the university to enhance total community involvement in the application of technology and engineering to medicine and health care delivery.

The unique feature was the establishment of a "community forum"—the Central Ohio Biomedical Engineering Community Council (COBECC). COBECC, covering seven counties in the Columbus area, is a separate, nonprofit association composed of members from industry, the university, public health departments, hospitals, private practitioners, and the like. It appears to be a very effective mechanism for stimulating interaction among the university, medical profession, health care institutions, professional societies, and large and small industrial firms. Through COBECC, formerly competitive vested interest groups and those who were heretofore strangers to each other are now actively collaborating to seek mutually beneficial solutions to community health problems in the Columbus region. Monthly meetings, topical workshops, the publication of a newsletter, the establishment of "special interest groups" suggested by specific interests welling up within its membership, and the provision of advisory consultation on projects and problems are some elements of COBECC activity. While COBECC itself does not engage in research and development, it actively encourages joint projects within its membership. Several such projects have been spawned.

The innovative COBECC mechanism stands as a meritorious prototype that other communities should examine carefully. It remains to

***Studies of Prototype Plans for Industrial Participation in the Developmental Phase of Engineers in Biology and Medicine*, Phase II Final Report, University of Wisconsin, Madison (February 1971).

be seen if COBECC's success is due to unique characteristics of its founders, or whether it is a model capable of transplant to other communities in the nation.

Other activities under Phase II at OSU were similar to those at the other two subcontractors. Workshops on selected topics were conducted, jointly sponsored by the university, COBECC, and professional societies. Curriculum and programmatic development leading to the establishment of the OSU Bio-Medical Engineering Center was accomplished. The center, administered by a director and interdisciplinary administrative and coordinating committees, includes over 90 staff members. It includes technology research groups, center projects, and industrially sponsored laboratories. The results of OSU's Phase II effort is fully documented in its final report.*

Conclusions and Recommendations

The results of the university prototype studies lead the committee to suggest the following considerations to those in government, university, health care delivery, and industrial sectors charged with furthering the national effort in biomedical engineering:

1. Development of training programs will continue for new engineering concept courses for biologists, premedical, and medical students, with an expansion at the master's level for allied professions. Fund requests for extensive course-development programs must be anticipated.
2. An increased involvement of qualified engineers as principal investigators in biomedical research projects will occur and should be supported, with collaborators from biology and medicine.
3. A new area for support may emerge from university biomedical instrumentation and systems groups that, with local industry, can expedite the introduction of new instruments, devices, and systems through channels.
4. The potential strong involvement of engineering colleges and universities in hospital design and planning, in the operation of health care units, and in solving community environmental problems points up a need for substantial support for these types of multidisciplinary activities. Guidelines and criteria establishing the policies and functions of these programs must ensure that they will enhance and expedite the beneficial applications of new engineering and technology for the public welfare.

**A Study of Effective Interplay of Engineering with Biology and Medicine in a Local Community*, Ohio State University Research Foundation, Columbus (October 31, 1970).

Industrial Aspects in Biomedical Engineering

The committee recognized at the outset that industry held a key to the furtherance of the application of modern technology to health care. CIEBM studied the role played by industry, the characteristics of the medical marketplace, and other factors that bear directly on industry interaction with other elements of the field. Committee activity was focused in its Subcommittee on Interaction with Industry and its Task Group on Industrial Activity. The former body used the mechanism of workshops to explore two issues: patent policy and the role of federal agencies or other intermediaries in biomedical engineering development. The task group, under the auspices of a separate National Institutes of Health task order, completed an in-depth study of 50 selected industrial concerns that provide biomedical engineering products or services.

Government Patent Policy

It is often stated that the patent policies of the federal government inhibit industrial research and development commitments. To investigate this subject, the Subcommittee on Interaction with Industry sponsored a Workshop on Government Patent Policy in which representatives of

federal agencies (HEW, DOD, VA, AEC, and NASA) as well as industry explained their positions and discussed the ramifications of government patent policy. In various ways, industry and university representatives indicated that federal patent policies disallowed proper financial rewards, while government officials attempted to explain the problems that arose within the Congress, the Executive Office, and the individual contracting offices. The policy structure was not accomplishing what generally is desired by all (i.e., the commercial utilization of inventions spawned by government research grants).

Like industry, universities have a need for research and development funds to reduce to commercial applicability a university-spawned invention, but the workshop deliberations suggested that government policymakers have been reluctant to grant exclusivity for background and/or foreground patents. The nebulous entity called "public interest" may well cause government officials to overprotect the "government's interest" by policing rather than releasing patent rights. Or it might be that business philosophies have penetrated to the point where the government believes it has to show a profit.* Whatever the reasons for government retention of patent rights, it was generally agreed that present patent policies are not producing the maximum exploitation of inventions.

The widely distributed proceedings of the workshop† summarized the consensus of the participants as follows:

> Sweeping changes in government patent policy were not suggested. . . . It is abundantly clear, for example, that government patent policy is neither rigid nor monolithic. There are nearly as many policies as there are government agencies.

Conclusions and Recommendations

Formal recommendations regarding patent policy were not made at the workshop, nor were any anticipated. However, several *aspects* of patent policy and its administration *were stressed* by the participants and are here summarized.

Government The Department of Health, Education, and Welfare

*Mr. Roland A. Anderson of AEC went so far as to say at the session that a certain company provides for royalty shares with "the inventor, the university and itself, but is unwilling to share income with the government."

†Committee on the Interplay of Engineering with Biology and Medicine, *Government Patent Policy–Report of a Workshop*, National Academy of Engineering, Washington, D.C. (1970).

should greatly augment its patent staff. Unreasonable delay in obtaining a decision on patent rights is an impediment to industrial participation in the health field.

A continuing examination of how patent policy serves the public interest is essential. Should all patents obtained on government contracts be placed in the public domain for all to use on a royalty-free basis? Or would public interests be served better by granting an exclusive license for a limited period of time, thereby providing some protection from unreasonable competition?

University Universities are well advised to adopt the HEW institutional patent agreement, which conveys certain patent rights to an invention *before* it is made. The university, like government, does not have facilities to produce products and should be enabled to arrange for exploitation of inventions through royalty arrangements with commercial firms.

Universities should make a thorough study of their mission and take it into consideration in formulating an employee patent policy.

Industry Manufacturers of medical instruments should obtain first-hand authoritative information about government patent policy.

In some instances it is possible for a commercial firm to obtain from HEW certain exclusive license provisions for future inventions at the time a contract is awarded, rather than waiting for the determination of patent rights after disclosure of an invention.

The factors involved in screening, developing, and testing the efficacy of a drug are different from those involved in the development of a medical instrument. Procedures followed in the development of a new drug as an approved marketable product are unique to the pharmaceutical industry. Government patent policy should be drafted to accommodate the differences.

The observations made at the workshop in September 1970, remain valid today.

Federal Agency Development

This workshop, implemented by the Subcommittee on Interaction with Industry, also took place in 1970. It utilized the technique of a case history study based on the Public Health Service Medical Systems Development Laboratory (MSDL) computerized electrocardiogram project.

The purpose was to examine the difficulties in conveying needs from the medical profession to the technologist and translating performance requirements into functional hardware.

In selecting a specific federal agency activity for the case study, it was desirable to identify a group whose purpose was to expand the use of technology into actual products or methods having practical applications in the health care environment. Further, it was desired to select a program that required participation from a large number of industry groups. These specifications were met by MSDL's program involving the transmittal of a patient's electrocardiogram over telephone lines to a central station where the signals are analyzed by a computer and the resulting diagnosis is returned to the sender in a matter of minutes. This program required the combined efforts of several sciences, disciplines, and professions. Specifically associated with the program in its various stages of development were representatives of government agencies, hospital administration, medical practitioners, the academic community, and the communications, data processing, and instrumentation industries.

It was the intent of the workshop to have all participants engage in a frank review of the influence and motivating forces associated with the specific agency program and as they relate to industry participation. Specific major topics follow:

1. *Industry–Agency Interaction* The forces and interests bringing the parties together, profit consideration and attitudes;
2. *Research and Development* Dividing lines between basic research and application engineering, applicability to other product interests;
3. *Market Evaluation* Research, council of advisors, engineering prejudices, merchandising prejudices;
4. *Production and Profit* Investment policy, production analysis, investing management, production continuity;
5. *Patents and Product Liability* Significance, timing;
6. *Safety and Standardization* Function and design, system interface;
7. *Point of Application* Cost, utility, user identity, system effectiveness;
8. *User Education and Communication* Selling, educating;
9. *Merchandising* Engineering dialogue vs. medical dialogue, manpower availability and training;
10. *Maintenance and Service* Modular construction, training specifics.

Conclusions and Recommendations

The workshop findings,* which closely parallel those of the Task Group on Industrial Activity, can be summarized in the expressed views of industry, on the one hand, and the medical device users, on the other.

Manufacturers desire the ability to adequately define product requirements to meet the needs of the users, introduce a product with a reasonable lead time from design to market acceptance, adequately predict the size of the market, and produce a product in a large enough quantity so that a reasonable sale price will provide a reasonable return on investment.

Users desire such products, providing they adequately substitute for manpower and/or improve on present procedure (although present procedure is not always well defined); the use of such products is safe under all possible controlled conditions and can be introduced by existing staff without concern over reliability or performance; and the acquisition and utilization of such products provide a definite advantage, in direct cost savings, increased efficiency, and/or increased effectiveness, to the user.

Task Group on Industrial Activity

Closely related to the Subcommittee on Interaction with Industry was the Task Group on Industrial Activity, which undertook a special study of industrial activity in biomedical engineering for NIH. It attempted to identify both constraints and inducements that affect private enterprise that produces and markets biomedical hardware and technological services. An indepth survey of 50 corporations served as the basis for the study that resulted in an often-referenced final report.†

Conclusions

1. Industry will respond quickly and effectively to develop, produce, and deploy biomedical engineering products and services when a reasonable profit can be forecast.

*The detailed proceedings of the workshop are available: Committee on the Interplay of Engineering with Biology and Medicine, *Federal Agency Development in Bio-Medical Engineering–Report of a Workshop*, National Academy of Engineering, Washington, D.C. (1973).

†Committee on the Interplay of Engineering with Biology and Medicine, *An Assessment of Industrial Activity in the Field of Biomedical Engineering*, National Academy of Engineering, Washington, D.C. (1972).

2. The present status of industrial activity in the biomedical engineering field is considerably below that which industrial capability can provide; the technology currently extant does not reflect the present state of the art in general.

3. The foremost impediment to the expansion of industrial involvement in biomedical engineering is a lack of economic incentives brought about by the unique characteristics of the market for products and services.

4. Industry is not engaged in biomedical engineering research to any significant degree, leaving that realm of activity primarily to university and government laboratories.

5. At present, industry is not sufficiently involved in the formulation of biomedical engineering needs and potential solutions. It is unaware of priorities in the needs for development, and there is inadequate feedback of medical and technical problems and capability that evolve from medical needs, advancing technology, and industrial resources.

6. The programs of the various government agencies involved in the research and development of biomedical products and services have not provided the necessary amount of encouragement for industry-sponsored research and development.

7. Industry is confused about the differing patent policies of the various government agencies, does not appreciate the flexibility inherent in current policies, and is reluctant to utilize government-funded research and development until greater assurance of protection of industrial investments is obtained.

8. There are certain products and services that require direct government development subsidy or government-industry development cost sharing, yet mechanisms to provide this type of funding have not been adequately implemented.

9. Standards for and acceptance of uniform clinical evaluation procedures required for successful development and marketing of biomedical products have not been achieved.

10. A lack of knowledge and appreciation by each profession of the contributions that the other can make in this interdisciplinary endeavor is a major problem in the medical and engineering professions.

11. There exists a paucity of educational programs and access to relevant information that would create a common understanding between the professions. This paucity exists for all levels of activity, professional and managerial, as well as at the supportive level of the nurse and technician.

12. Qualified engineers have lacked the opportunities to work and accept engineering responsibilities in the medical and health care field;

the need for professional engineering competence in these environments appears to be unrecognized.

13. The biomedical engineer has not yet adequately demonstrated or been given sufficient opportunity to demonstrate his ability to contribute within the industrial sector (i.e., in industrial employ).

14. While NIH support of Ph.D. biomedical engineering training programs has been directed toward the national need for competent research-oriented personnel, there is a lack of a sufficient number of competent product- and design-oriented biomedical engineers, trained at the B.S. and M.S. levels, who can function effectively in the industrial setting.

15. There is inadequate interaction between government agencies and the biomedical engineering industry, resulting in each having a lack of appreciation of the responsibilities, problems, and programs of the other.

16. The capability of and need for engineers to serve in responsible leadership positions in government biomedical research and development programs have not been fully recognized within government agencies.

17. Hospital and clinical personnel are inadequately trained in the use, operation, and maintenance requirements of technological products and services, and administrators do not appreciate the existence or impact of this inadequacy.

18. There are inadequate voluntary and regulated standards for the performance and safety of biomedical products and services, and effective enforcement procedures are yet to be established.

Recommendations

The task group made specific recommendations, addressing each to NIH, other government agencies, and/or the private sector (Table 3). The major recommendations of the task group, however, follow:

1. It is therefore the highest recommendation of the Task Group on Industrial Activity that an overview body, perhaps known as the National Biomedical Engineering Evaluation Panel, be immediately established (to coordinate the national effort).

2. The benefits to be derived by a more balanced involvement of engineers with medical scientists in biomedical research would contribute to the definition, identification, concept development, and applied research of devices and processes that could be of direct benefit to the health of the nation.

TABLE 3 Specific Recommendations of the Task Group on Industrial Activity

Recommendation	Implemented by NIH	Other Government Agencies	Private Sector
1. Encourage and contribute to the establishment and support of the National Biomedical Engineering Evaluation Panel.	X	X	X
2. While continuing to fulfill its primary responsibility in basic research, NIH should broaden and make widely known its interest and responsibilities in the development of biomedical engineering products and services. A greater effort toward goal-oriented research would be consistent with this objective.	X		
3. Expand government inhouse engineering competence by augmenting the biomedical engineering staff in the intramural and extramural programs of each institute and agency.	X	X	
4. Require realistic engineering involvement in government grants and contracts. Allowing engineers a greater opportunity to serve as principal investigators (in lieu of medical researchers) would be consistent with this objective.	X	X	
5. In addition to maintaining the current Ph.D. training programs, support university trainee programs for design- and product-oriented biomedical engineers at the B.S. and M.S. levels.	X	X	X
6. Provide for engineering internships at NIH and other medical centers (both government and civilian) for practicing engineers from industry and for participants in the biomedical engineering programs of universities.	X	X	X
7. Provide for internships in industry to better identify the value and deficiencies of biomedical engineers in industrial situations.	X	X	X
8. Define and make widely known the responsibilities of each government agency in the research, development, evaluation, and deployment of biomedical engineering products and services.	X	X	
9. Encourage the developmental phase of high-priority biomedical engineering products by industry.	X	X	
10. Promote greater university-industry interaction in the development of biomedical products, the utilization of basic research, and the training of biomedical engineers.			X

TABLE 3 (continued)

Recommendation	Implemented by NIH	Other Government Agencies	Private Sector
11. Provide means for clinical evaluation to promote market acceptance of biomedical engineering products and services.	X	X	X
12. Unify the application of patent policies to profit as well as nonprofit organizations and develop procedures (e.g., exclusive licenses) to encourage private risk capital investments in product development and deployment.	X	X	
13. Provide for an organization similar to the FDA to develop and regulate, along with industry, standards and safety measures for biomedical products and services.	X	X	X
14. Develop closer relationships between industry and the medical profession during the specification of product needs by expanded use of medical consultants in industry and collaborative industry-hospital and industry-clinic programs.			X
15. Create greater employment opportunities within industry to permit the demonstration by competent biomedical engineers of the contributions that they can provide.			X
16. Recognize the uniqueness of the biomedical engineering marketplace and develop the specific managerial techniques and personnel required to operate effectively within it.			X
17. Develop means to properly train the users of biomedical engineering instruments and provide for adequate maintenance, calibration, and repair services.		X	X
18. Provide support and designate a body (e.g., the National Biomedical Engineering Evaluation Panel) to conduct a study of the attitudes and position of the medical community toward engineering comparable to the study made of industry by this task group.	X	X	

3. The task group, therefore, recommends that there should exist a (lead) government agency with a primary responsibility to develop and stimulate the deployment of biomedical engineering technology.

A Pilot Study of the Delivery System Perspective on Engineering Technology in Health Care

Background

With its university prototype study, the activities of the Subcommittee on the Interaction with Industry and the 50-company indepth study by the Task Group on Industrial Activity, the committee became well aware of the attitudes, positions, and constraints of the industrial sector in biomedical engineering. Although many qualitative opinions have been voiced and echoed, a similar effort to collect data on the attitudes toward technology and industry of practitioners and administrators in health care delivery had not been accomplished. In fact, one of the recommendations of the Task Group on Industrial Activity was that there be conducted "... a study of the attitudes and position of the medical community toward engineering and technology comparable to the study made of industry by this Task Group."

This need for an objective assessment of the perceptions of health care delivery system decision-makers toward engineering and the utilization of technology was also voiced by CIEBM's Subcommittee on Engineering in Clinical Care and by the Phase II subcontractors. All felt that such a study should be nationwide in scope.

Two of the Phase II subcontractors, The Ohio State University and the University of Wisconsin, proposed that as a final portion of their Phase II efforts they perform pilot studies in their own locales (Co-

lumbus, Ohio, and Madison, Wisconsin) of the type suggested. Accordingly, the two universities were awarded small subcontract extensions to assess medical community perspectives toward technology, engineering, and industrial suppliers and to disclose medical attitudes toward the roles that engineers might play in the health care delivery system.

It was recognized from the outset that the small study, primarily conducted by means of interviews, would be primitive and that the results could not be interpreted as representing a national picture. However, the pilot study could provide a measure of initial planning, could serve to verify or refute the need for a larger effort, and could test some investigative procedures. Thus, the subcontract extensions were awarded and the two universities undertook the task.

In the process of their earlier Phase II studies, both subcontractors had contacted some local hospitals, clinics, and private practitioners. In the pilot study some of these institutions were revisited and, in addition, representatives of several new institutions were interviewed.

The summary results presented below were derived from the totality of experiences of the subcontractors as they have related with the health care delivery segments in their respective regions. In addition, it should be noted that the community-wide programs being developed at each of the two locations have certain unique characteristics and objectives. Thus while a large portion of the information collected by the two groups can be readily integrated and synthesized, some of the findings are pertinent to only one of the two groups.

Results

The findings of the two groups as discussed in their two reports are very similar and support most of what has been hypothesized about the general lack of understanding of technology. In general, they found both an awareness and a wariness of technology: The medical community knows that technology can and does help to solve their problems, but at the same time it does not have a sound understanding of technology, the principles of engineering, and the role of a professional engineer. The practitioners are result-oriented; they want clear evidence of demonstrated value of a new technology. They are not prone to explore the use of new techniques that hold promise before positive, effective, and safe results have been shown.

The delivery system practitioners and administrators have a difficult time specifying their needs in the precise manner desired by engineers. Further, they are not fully aware of the various professional responsi-

bilities and capabilities of professional engineers; in fact, such professionals are often confused with plant maintenance personnel.

The Ohio State report concludes and recommends:

The results of the pilot study indicate that a basic understanding of the attitudes of the health care delivery system toward technology can be obtained through this type of interview-discussion approach. Thus, it is recommended that the apparent results of this local effort be validated or broadened through a similar national survey carefully designed to include effects of all geographic variations within the United States.

It is therefore recommended that:

A study should be carried out to determine on a national basis the attitudes toward and the needs of technology in health care delivery as seen by the practicing physician, the hospital administration, and the community health care delivery planning groups.

The Wisconsin report carried no recommendations.

Engineering in Clinical Care

Background

The Subcommittee on Engineering in Clinical Care was formed in the spring of 1970 to consider ways to integrate and gain acceptance for "clinical engineering"—i.e., engineering applied in hospitals, clinics, and similar diagnostic and therapeutic health care institutions. Emphasis was placed on improvements in service functions as well as on the research necessary to produce imminent results and solutions. Engineering involvement in more basic research was not investigated by this subcommittee.

The subcommittee used meetings and workshops to accomplish its objectives. Several meetings of the group produced a common view of the basic steps that should be taken to move the emerging profession of clinical engineering from its infancy to a recognized and widely used component of health care delivery. Four major elements were defined and are summarized below.

Categorization of the Roles and Responsibilities of Clinical Engineers

The wide range of roles and responsibilities encompasses the technician's assistant who may only require a high school education to

Ph.D.'s working with the highest level of a medical team in a large university medical center. In between are 2-year biomedical engineering technicians (BMET) and bachelor's and master's level professionals who fulfill numerous functions, all under the generic mantle of "biomedical" or "clinical" engineering.

A characterization of these varieties of functions would benefit from a degree of formalization. Today, for example, confusion reigns over what kind of person should be given responsibility and authority for equipment maintenance in a hospital. This has often been talked of as a job for the biomedical engineer or the BMET. The formalization could take the form of a set of generalized (albeit mythical) job descriptions to cover major points on the spectrum. These descriptions would contain a statement of the functions of the position, the authority invested in the incumbent, the level of training and competency required, and the means of certifying that competency.

A set of such job descriptions would provide a basis for open debate, as there certainly will be controversial issues exposed in any such categorization. The debate should involve the technologist, the academician, and physicians and administrators from the delivery system. While they may never secure unanimous approval, the set of descriptions (as modified and commented upon in public discussion) would be useful, indeed required, for an assessment of national needs.

Assessment of National Clinical Engineering Manpower Needs

National manpower requirements, both current and projected, for each of the major roles of clinical engineers (i.e., those defined in the generalized job descriptions) should be assessed to determine the adequacy of training program outputs. For example, will there be a need for many more BMET's or graduate biomedical engineers? Only by making a realistic estimate of needs can the educational component be optimized to provide a supply that meets demand, both in numbers and in capabilities.

Certification of Competency

There needs to be a way to certify that an engineer or technician is capable of operating effectively in the clinical environment. Such certifications have two purposes: to assure the individual's competency to assume his assigned responsibilities that can directly or indirectly affect

patient care and, second, to provide that person with credentials that are recognized by his cohorts in both the engineering and medical professions and that provide him with the status and financial remuneration commensurate with his duties.

A model for such certification might be that which has been used by the medical profession. A training institution by means of a diploma states that a graduate has satisfactorily completed the curriculum, a state licensing agency certifies the individual's competency to practice in the state, and national boards and academies examine and certify states of competency.

Clearly, not all means of certification are desired or necessary for all functional levels, and the design of a certification schema would benefit from open discussion. It should be noted that with its recent introduction of a certification program for BMET's and clinical engineers as well, the Association for the Advancement of Medical Instrumentation (AAMI) has assumed the needed initiative.

Acceptance of Clinical Engineers

If clinical engineering is to expand its value, the delivery system decision-makers must be convinced that engineers, technicians, and the technology they can apply are needed assets in health care. That this is not yet the case is supported by the fact that it is mostly the biomedical engineering community that pleads for more and better trained people. Though they cry for more physicians, physician's assistants, nurses, emergency medical paramedics, and the like, very few physicians and hospital administrators are heard pleading for more biomedical engineers. They have not generated the pressures (by creating unfilled job vacancies) that would stimulate and upgrade the current production of engineering talent.

To accomplish this, the biomedical engineering profession must extend its success stories beyond its own confines. The value of clinical engineering by opinion-makers of the health care delivery system must be documented and made available through meetings and journals of the medical academies and the hospital associations. The biomedical engineering community must identify and persuade some champions from within the leadership of the delivery system to carry to their brethren knowledge of engineering applications, the costs involved, and the derivable benefits.

In short, the greatest stimulus to clinical engineering would be a significant expansion of the market for its practitioners. This can only

come about when those responsible for the securing of engineering services—the delivery system decision-makers—become convinced that those services are needed and cost-effective.

Conferences

The subcommittee chose to disseminate these views and subject them to public debate by organizing and conducting two conferences. The first was under the auspices of the Engineering Foundation and was held July 19–23, 1971, in Deerfield, Massachusetts. There, approximately 60 representatives of the engineering, medical, and hospital administration professions from across the nation explored and refined these issues in a series of plenary sessions and intensive workshops. While no formal proceedings are prepared at such Engineering Foundation conclaves, the week served to assess the field and its needs as developed by the subcommittee.

At the Deerfield conference, the subcommittee decided to take action to further the acceptance of clinical engineering by conducting a second conference specifically aimed at the health care delivery decision-maker. The intent was to document in a conclusive fashion the value of the various benefits that clinical engineering can bring to health care delivery. This conference, sponsored by AAMI, resulted from a 2-day tutorial, "The Clinical Engineer in Today's Hospital," held October 27–28, 1972. Over 200 representatives (largely hospital administrators and physicians) heard case histories of clinical engineering projects and participated in panel discussions that examined clinical engineering in a variety of settings.

A summary of the tutorial is provided in the inaugural issue (January 1973) of AAMI's *Clinical Engineering Newsletter.* This monthly publication had its genesis in the deliberations of the subcommittee and, it is hoped, will be an ongoing instrument to further the acceptance of clinical engineering.

Sensory Aids

Background

The mobility and reading problems of the visually impaired and the speech and language problems of the hearing handicapped were the concern of the Subcommittee on Sensory Aids. The subcommittee advised the committee on the present status and needed developments in this field.

In pursuit of its study, the subcommittee has sponsored two international workshops: "An Evaluation of Mobility Aids for the Blind" and "Sensory Training Aids for the Hearing Impaired." The so-called "Easton conference" on sensory aids for the deaf, held in 1970 in Easton, Maryland, has become a landmark: Over 3,000 copies of its proceedings were printed, it has been widely referenced, and its key recommendations have influenced the thrust of several subsequent federal agency program efforts, including those of the National Institute of Neurological Diseases and Stroke.

In addition, the subcommittee developed a prospectus* for an action plan to focus efforts at the national level on sensory aids research, development, evaluation, and deployment. Organizational forms were

**Sensory Aids for the Handicapped—A Plan for Effective Action*, National Academy of Engineering, Washington, D.C. (December 1971).

suggested that could link research and social services. A program was outlined that could be conducted within the Academy to assist in furthering the objective of creating an integrated national effort.

Throughout its existence, the subcommittee has been asked to identify vital areas in sensory aids research and development that warrant attention. These requests have come both from federal and private sponsors of research and from investigators in the field desiring to initiate meaningful projects. The subcommittee met this need with the publication of two reports* that annotated 17 important projects in the area of sensory aids for the visually impaired and 11 for the hearing impaired. As the report titles suggest, not all projects listed involve fundamental research. Also included are projects such as demographic surveys, public information programs, and the establishment of sensory aid centers that, in the view of the subcommittee, are immediate and essential elements of a balanced national program in sensory aids.

Results

The five reports (two workshops, the action plan, and the two annotated lists) have been widely distributed. Presented below are brief highlights of their contents.

Evaluation of Mobility Aids for the Blind

This conference focused on the problem of assessing the utility of obstacle detectors and environmental sensing devices. Used as examples for case study were three devices currently available in small quantities: the laser cane, the pathsounder, and binaural sonic glasses. The results of evaluation attempts were reported and discussed and new techniques (e.g., computer mobility simulator, tactile mobility display) were proposed.

The conference concluded:

Since the end of the Second World War there has been a growing effort directed toward the use of technology in the development of additional mobility aids. However, the blind have as yet derived essentially no benefit whatever from our enhanced technological capacity to explore the environment by means of techniques such as radar, sonar, laser, etc. The reasons for this stem partly from a lack of ade-

**Selected Research, Development and Organizational Needs to Aid the Visually Impaired* and *Selected Research, Development and Organizational Needs to Aid the Hearing Impaired*, National Academy of Engineering, Washington, D.C. (May 1973).

quate resources to exploit these technologies and partly from an inadequate basic understanding of the principles governing the effective presentation of visual information to a blind man's auditory or tactile senses. Without knowledge of the best ways to process and display information for given tasks, much experience must be gained by trial and error methods not all of which can be applied within the laboratory. This creates an important shift of emphasis in the strategy of mobility aid research and development which cannot be stressed too strongly. The major consequence of this shift is that evaluation and training techniques must be invoked more frequently to provide empirical data to guide further research and hence training and evaluation become a more intimate and important part of research and development than is customarily implied by the term R&D.

Sensory Training Aids for the Hearing Impaired

This international conference brought together engineers, speech scientists, teachers of deaf children, educators of teachers of the hearing impaired, and otolaryngologists to discuss sensory aids for deaf children. Hearing aids, speech training aids, computer-aided instruction, and the need to better evaluate all such systems were covered in the deliberations.

The conference concluded with the attendees charting a course for the future by constructing a series of 26 recommendations that covered (1) basic research in speech and language, (2) development and evaluation on sensory aids, and (3) management and administration.

The proceedings are now used in many of the leading training centers for teachers of the deaf. Thus the product of the conference in itself is helping to solve a key problem revealed at the conference:

> The most important realization to emerge, however, was the identification of a tremendous chasm that exists between scientists and teachers. The scientists were unaware of the day-to-day problems faced by the teachers, and the teachers were unaware of what was known and—even more important—what was unknown in the areas discussed. There was general agreement on the need for the education of both sides in each other's problems.

Sensory Aids for the Handicapped—A Plan for Effective Action

This proposal to integrate the nation's fractionated and undersupported programs in the sensory aids area first discusses the needs of the deaf and the blind and how sensory aids have promise of meeting some of them. It notes that sensory aids progress has been impeded by three factors: the complexity of the field, the lack of coordination of the many disparate people and organizations working on the problem, and

an unpredictable and small market encompassing an economically disadvantaged subpopulation (of handicapped people).

The report recommends a comprehensive program, coordinated at a few sensory aids national centers, that would embody four key elements: information collection and dissemination, research and development, evaluation and deployment, and funding. Various types of organizational arrangement, together with their advantages and disadvantages, that could accomplish the required national focus and coordination are suggested in the action plan.

Finally, the report recommends a 2-year program, conducted by the Academy, that would result in a detailed national sensory aids program plan, thus initiating its implementation.

Selected Sensory Aid Needs To Aid the Visually and Hearing Impaired

These two lists of projects, which in the view of the subcommittee merit immediate attention, outline the following tasks:

Visually Impaired

- Demographic survey of reading aid needs
- Demographic surveys of vocational opportunities
- Multidisciplinary exchange of information
- Public information programs
- Sensory aids centers
- Research on sighted reading
- Research on pattern processing
- Automated reading services
- Pilot studies of the usefulness to the blind of automated reading services
- Devices to aid in reading visual displays
- Research on requirements in automated braille production
- New reading and mobility aids
- Computer-aided studies of mobility
- Tactile stimulators
- Definition of visual capabilities among the partially sighted
- Aids for the partially sighted

Hearing Impaired

- Demographic surveys of the hearing impaired and their needs
- Public information programs
- Multidisciplinary interaction
- Sensory aid centers

- Deployment of existing sensory aids
- Fundamental research on speech and language acquisition in hearing impaired children
- Quantification of residual perceptual capacity
- Improvement of diagnostic techniques
- Development of evaluation procedures
- Evaluation of existing sensory aids
- Improvement of conventional hearing aids

Biomedical Engineering in Selected Foreign Countries

Background

The National Institutes of Health asked the committee to collect information on the nature and level of biomedical engineering activities in selected foreign nations so that techniques and approaches that might be relevant to our nation are not overlooked. To meet this request, knowledgeable consultants were retained to analyze and report on the situation in each of five countries. The countries and the dates during which the consultant reports were written are Denmark (1970), Japan (1970–1971), the Soviet Union (1968), the United Kingdom (1971), and West Germany (1968).

A summary of the contents of the reports is provided below. It must be noted that while the committee reviewed the documents, no extensive deliberations of the committee accompanied this information collection task. Nor have the earlier reports been updated to reflect new developments in the respective foreign countries.

Summary

In considering the various national approaches to the advancement of biomedical engineering, it is most important to recognize that this is

only one element—though an essential one—in any health care system. It is also worth observing that the object of a health care system is the maintenance of a healthy population, not solely the cure of disease. The products of biomedical engineering are increasingly essential in both preventive and curative medicine: The portable x-ray screening unit is as equally important as the fixed-radiation therapy unit.

Yet, even in the United States it is frequently observed that there is a considerable gap between the state of the art of the various engineering disciplines and the engineering that is actually applied to the problems of medicine and biology. In each of these other countries that gap is also a principal characteristic of the current state of the practice of medicine, although its nature varies greatly among the countries. The existence of this technology gap in a world that put men on the moon and transmits live color television instantaneously from continent to continent and, moreover, in an area (namely, health) in which each member of the human race has a very important stake, would be astounding if it were not so widespread and of such long standing.

In considering the five reports and Table 4, which summarizes their salient features, it is important that the social context of the respective countries, which the authors do not thoroughly detail, be borne in mind. There are large differences in many basic social and cultural conventions: the meaning of individuality; the definition of terms such as "doctor," "promotion," and "research"; the expectations of the role of government and other major elements of society; and the economic factors such as the roles of government and private financial institutions in making funds available for research, development, and production of medical devices.

Japan, for example, appears to have a western style social structure, but it does not operate in the western manner: "Consensus" is the most important word, not "leadership," "direction," or "administration." Ostensibly, the advancement of biomedical engineering in Japan depends on a decision and subsequent action by the Ministry of Welfare. Actually, that apparent decision and action will be, when they come, merely a reflection of a consensus among all those concerned that it is now time to actively throw the weight of the country behind advancement of the field.

The Ministry of Welfare, therefore, does not "lead" the effort as might be the case in western countries, but in fact allows an already established trend—a trend in which the Ministry itself may have been heavily involved for many years, albeit behind the scenes. In western countries such as the United States, an attack on a problem is likely to result in the establishment of an institution that is then charged

TABLE 4 Biomedical Engineering in Selected Foreign Countries

Denmark

National Policy and Decision-Making: Most decisions in health care are made on the local or institutional level. The system is based on initiative from the local level and is decentralized. The National Health Service of the Ministry of the Interior provides advice.

Financing: University research and development is mostly funded as a part of the institution's budget. About 7-10 percent of Medical Research Council funds (which totaled $1 million for 1970-1971) go to BME (as do lesser amounts from the three other Danish research councils). About 65 percent of hospital expenditures are paid by the National Health Service; 35 percent, plus capital investments, by the counties and cities. Some development funds for industry are available through the national Fund for Technological and Industrial Research and Development.

Training: There are few formal courses in BME, and no formal academic degree available in the field. There has been no difficulty in recruiting students for the courses available. The Danish Biomedical Engineering Committee's Subcommittee on Education initiated experimental courses in the fall of 1970. There is a need for BME technicians.

Professional Environment: BME was largely unrecognized in Denmark until 1964; traditionally, engineers had a service role in hospitals. Now some hospitals have BME departments that experience good cooperation with medical departments. In the Copenhagen hospitals, biomedical engineers have nearly equal status with medical professionals and stimulate the physician's interest in BME.

Production: About 90 Danish firms with a wide range of products engage in BME and are heavily dependent on export.

International Influence: In addition to having a largely export-oriented industry, considerable effort has been devoted to Nordic cooperation by the DBMEC, which published the *Nordic Guide* in 1969, a register of biomedical engineers and companies in the four Nordic countries.

Professional Societies: The Danish Biomedical Engineering Committee (DBMEC), established in 1966 by the Danish Academy of Technical Sciences and the Medical Research Committees, is a focal point of BME promotion and communication. DBMEC has committees for education, industry, and patient safety problems. In a 1970 poll, most BME personnel preferred the DBMEC structure to the formation of a biomedical engineering society.

Marketing: The DBMEC industrial committee brings together the diverse membership of the DBMEC, officials of the National Health Service, and various members of industry, to provide marketing of goods and services both within Denmark and internationally.

Japan

National Policy and Decision-Making: Once a consensus develops, government action can follow swiftly. In biomedical engineering (BME), this would be led by the Ministry of Welfare, followed by other ministries. A particularly strong element

TABLE 4 (continued)

in such a consensus would be the position of the Japanese Academic Conference (established by national law).

Financing: Some funds are available through the budgets of various ongoing institutions; however, action by the Ministry of Welfare will ensure adequate support to reach the consensus-identified goals. (In 1959, the Ministry of Welfare attempted, without a consensus, to establish a national medical technological lab and failed in its attempt to get funding.)

Training: BME research is largely confined to four academic institutions. The report does not cover training and recruitment, but the general high level of activity indicates little difficulty in this area.

Professional Environment: A "medical engineering research establishment" exists. It is basically medical, but has a heavy involvement of engineers (especially electronic engineers). There is a general recognition of the worth of BME among these people.

Production: The Ministry of Welfare licenses manufacturers of medical tools and equipment and issues permits for medical equipment factories. Grants for development and facility modernization are available from the Ministry of Commerce and Industry.

International Influence: The Japan Medical Equipment Conference is an active member of the International Federation of Medical and Biological Engineering (IFMBE), formed in Paris in 1958. Expansion on an international scale is pursued aggressively.

Professional Societies: BME-oriented societies date back to 1950 in some areas. The Japan Medical Equipment Conference (JMEC), a part of the Japan Academic Conference, holds regular meetings and publishes a journal; it brings together 10 BME-related "conferences" in specialized areas.

Marketing: The JMEC serves as an avenue of both intellectual and industrial communication. There appears to be ready acceptance of new items and demand is expected to increase greater than fivefold by 1975. In 1969, BME was a roughly $93 million industry, having enjoyed an 18.7 percent annual growth for the preceding 8 years.

Soviet Union

National Policy and Decision-Making: Production decisions for biomedical equipment are made by the relatively new Ministry of the Medical Industry, which is intended to cooperate with the Ministry of Health Protection (MHP) through the Central Committee of the Communist Party and the Soviet Ministers.

Financing: Funds for research, development, and investment in equipment are provided through state channels, but production of biomedical equipment is on a "profit/loss basis" by individual factories.

Training: Low salaries in the area of BME apparently make it difficult to retain graduate engineers, and there is a consequent shortage of personnel. MHP planned to train physicians and hospital administrators in the application of medical engi-

TABLE 4 (continued)

neering and to train instructors in BME. Radio amateurs are encouraged to develop medical devices, mainly as a method for training engineers and technicians in BME.

Professional Environment: Since the principal concern is still with supplying the basic and well-understood needs of hospitals, there has apparently been little interaction of engineers and physicians in the area of R&D. Generally, inadequate performance of available medical devices may considerably prejudice Soviet doctors against work with engineers.

Production: The world's first medical industry was founded in the year 1719 by Peter the Great and still operates in Leningrad as the "Krasnogvardeyets" (Red Guards) plant. Today, all BME production is planned by the state, though with mixed results. In the 1960's the industry was reorganized into autonomous "firms" patterned after western corporations in hopes of improving productivity and quality.

International Influence: The Soviet Union imports a great deal of BME equipment (especially from Czechoslovakia, Hungary, and the German Democratic Republic). It exerts very little influence on other countries in BME.

Professional Societies: In 1968 there were plans to establish an All-Union Scientific Medical Engineering Society to unite all those in the Soviet Union with an interest in BME. At the time, the U.S.S.R. published six periodicals dealing directly or indirectly with BME.

Marketing: The Ministry of the Medical Industry is responsible for research, development, and production of drugs, instruments, and other medical devices and supplies. At present, demand exceeds the supply even for basic items, and research takes second place to production.

United Kingdom

National Policy and Decision-Making: National policy is set at the departmental or ministerial level, apparently on the basis of advice from the national Medical Research Council (MRC). There is no formal BME input to this process. The MRC reviews all medical research.

Financing: Most R&D funds are supplied by the Medical Research Council, which is supported by Parliament through the Department of Education and Science; additional funding comes from the department of Health and Social Security and a number of smaller sources.

Training: Many present workers in BME are qualified by engineering experience received during World War II, rather than by formal training. All present BME training is on the postgraduate level (leading to an M.Sc. or Ph.D. degree); there is a shortage of instructors, but graduates more than fill the demand.

Professional Environment: Most research and development work is done in academic institutions and governmental laboratories where BME personnel seem to enjoy relatively good relations with medical personnel, in part because of the official recognition of BME by the government and academic institutions.

Production: The BME industry is small and of poor profitability and shows little willingness to risk capital on the introduction of new items. Some items (i.e.,

TABLE 4 (continued)

hearing aids, artificial limbs) are produced by public or quasi-public organizations.

International Influence: British scientists and engineers contribute substantially to international conferences; although most work is U.K.-oriented, British products and ideas are found in many foreign hospitals and laboratories.

Professional Societies: In addition to a vigorous national Biological Engineering Society, there is the U.K. Liaison Committee for Sciences Allied to Medicine and Biology with 18 subscribing organizations. A literature information services (Fast Access Information Retrieval) was established by the National Institute for Medical Research, BME Division.

Marketing: Hospital budgets for the purchase of BME equipment often consist of the surplus left over after standard items are purchased and, thus, are usually quite small. Some minor central control over purchasing is exercised by Department of Health and Social Security (DHSS), more centralized purchasing of BME equipment is forecast.

West Germany

National Policy and Decision-Making: The report recognizes that BME was neglected as a specific field; thus there has been no history of decision-making in this area. The report seems to look forward to a rapidly emerging combination federal government and institutional decisions to foster development of BME. This has, in fact, occurred.

Financing: Both medical research and clinical care of patients are essentially financed from government or quasi-government funds (endowments). However, other private sources of money are also very important.

Training: No educational programs existed in 1968 for BME. Those engineers who developed a capability found very few positions in which they could put their experience to work; one technical institute with a medical faculty was planned.

Professional Environment: There was apparently very little interaction; associate positions for biomedical engineers were nonexistent at medical research and training institutions. Occasionally, engineering institutions have successfully cooperated with medical institutions, but without modification of either institution or formation of new, joint programs.

Production: The BME industry was apparently quite large (second only to the United States), but not fast-growing. Development was stifled because of the immense financial risks that fall entirely on the individual firm.

International Influence: Because of the lack of innovation, German BME apparently had little influence on other countries. However, the report cites other nations repeatedly as examples, suggesting that there was considerable awareness of advances achieved abroad and change in the wind.

Professional Societies: While a German Society for Biological and Medical Electronics existed, the general lack of professional interaction, of career opportunities for biomedical engineers and of technical knowledge on the part of M.D.'s restricted

TABLE 4 (continued)

the flow of ideas, thus confining them to a relatively elementary level. There was a general lack of reliable information sources.

Marketing: Apparently, there was fairly widespread use of the standard products of BME, but little interest in innovation or the development of new devices—again, due to the lack of technically competent M.D.'s. The utilization of available equipment was restricted due to a lack of both engineers and technicians.

with "doing something"; in Japan, the appearance of the institution is a sign that something has been done.

The Danish approach apparently depends primarily on local or individual initiative, though this is backed up by a nationwide system of support for all aspects of the health care industry. While Denmark has a National Health Service and a "cradle-to-grave" system of social welfare, considerable diversity is evidenced within the country among the various locally run hospitals and academic institutions.

The United Kingdom seems to follow its traditional role of stressing individual initiative, which is dependent on the actions of individual citizens not only for the development of particular items of technology but also for the promotion and establishment of the institutions within which technology may be advanced. Thus, the author of this particular report cites his own experience in establishing a biomedical engineering division within the British National Institute for Medical Research and discusses other British institutions on the basis of his own personal experience. Funding in Great Britain also seems to follow this individual initiative, giving the appearance of centralized control while maintaining a system permitting diverse individual initiative.

The Soviet Union seems to find itself in a somewhat ambiguous position: Both initiative and funding come entirely from a central state bureaucracy, but implementation depends heavily on the drive and actions of individuals in the field. In this regard, the U.S.S.R. may be diametrically opposed to Japan: Institutions are established immediately on identification of a problem, followed by a shakedown period in which ways are sought to make the institutions work (and occasionally in their demise). Only after this process is completed does effective work toward solution of the originally perceived problem begin (although the establishment/shakedown process is not necessarily a long one.

The Soviet Union has established a series of western style biomedical engineering production organizations that must operate on an individual

profit and loss basis. These are established and financed by the state, but must stand on their own. On the other hand, the Soviet Union seems to stand out also for the fact that medical practitioners—the deliverers of health care—seem to form the most helpful force for the advancement of the field through their demand for high quality, adequate medical equipment, and their sharp criticism of the system when it fails to make such devices available to them and consequently to their patients.

The report on the situation in the Federal Republic of Germany may be one of the most tantalizing in that it suggests a great potential, but assumes (since it was written by a German for Germans) a rather good knowledge of the sociopolitical and academic structure of West Germany on the part of the reader. For example, while the costs of existing and proposed projects are often mentioned, the potential sources of fund[illegible] not discussed. Happily, there has been a very rapid expansion of German activity in biomedical engineering since this report was written in 1968.

Perhaps one further observation ought to be made. Every one of the reports suggests, without specifically stating, that within each country there is a feeling that it must be equal in every respect, including development, to every other nation. If the United Kingdom has it, so must Japan. If the United States is strong in instrumentation, Germany must be also. Thus, if there are five nations, there must be five developers of the wheel—not to mention the x-ray device, EEG recorder, or defibrillator. Among the developed countries, at least, competition will remain the rule rather than the exception.

Table 4 displays a comparative summary of the reports of the five countries in each of eight topical areas.

Appendix A
Reports of CIEBM

Reports Issued by the Committee

All reports available from the National Academy of Engineering unless otherwise specified.

1. *Prototype University Plans for the Development of Biomedical Engineering,* April 1969.
2. *A Study of Technology Assessment,* Part III, Chapter 3, "Multiphasic Health Screening," July 1969.
3. *Engineering and Medicine,* a symposium sponsored by the National Academy of Engineering, 1970..
4. *Government Patent Policy,* 1970.
5. *An Assessment of Industrial Activity in the Field of Biomedical Engineering,* 1971.
6. *Evaluation of Mobility Aids for the Blind,* 1971.
7. *Sensory Training Aids for the Hearing Impaired,* 1971.
8. *Sensory Aids for the Handicapped–A Plan for Effective Action,* 1971.
9. *Selected Research, Development and Organizational Needs to Aid the Hearing Impaired,* 1973.
10. *Selected Research, Development and Organizational Needs to Aid the Visually Impaired,* 1973.
11. *Federal Agency Development in Medical Engineering,* 1973.
12. *Study of Aerospace Technology Utilization in the Civilian Biomedical Field,* 1973, and three supplements: "Report on Pulmonary Care" (1970), "Report on Cardiovascular Care" (1970), "Emergency Medical Communications" (1972).

Reports Written under Direction of the Committee by Subcontractors to the Academy

1. *Prototype Proposal for a Regional Bioengineering Program,* College of Engineering and School of Medicine, University of Washington, 1968.
2. *The Interplay of Engineering with Biology and Medicine,* University of Virginia, 1968.
3. *A Study of the Interplay of Engineering with Biology and Medicine in the Metropolitan Area of Columbus, Ohio,* College of Engineering and Medicine, Ohio State University, and the Columbus Laboratories of Battelle Memorial Institute, 1968.
4. *Harvard University–Massachusetts Institute of Technology Program in Engineering and Living Systems,* Joint Study Steering Committee, Harvard University and the Massachusetts Institute of Technology, 1968.
5. *Report on the Interplay of Engineering with Biology and Medicine,* Johns Hopkins University, 1968.
6. *Health Care Needs and Prototype Plans for Technology Health Systems Interaction in Western Pennsylvania,* Biotechnology Program, Carnegie–Mellon University, 1968.
7. *Interim Report on the Interplay of Engineering with Biology and Medicine,* Johns Hopkins University, 1970.
8. *Interim Report - Phase II Study of the Interplay of Engineering with Biology and Medicine,* University of Wisconsin, 1970.
9. *Progress Report on Phase II Study of the Effective Interplay of Engineering with Biology and Medicine in a Local Community,* Colleges of Engineering and Medicine, Ohio State University, and the Columbus Laboratories of Battelle Memorial Institute, 1969.
10. *Status Report –Prototype Proposal for a Regional Bioengineering Program,* Bioengineering Programs, University of Washington, 1970.
11. *Progress Report, Joint Harvard–MIT Program in Health Sciences and Technology,* Harvard University and the Massachusetts Institute of Technology, 1970.
12. *A Follow-up Report, The Interplay of Engineering with Biology and Medicine,* University of Virginia, 1970.
13. *Progress Report on Carnegie–Mellon University Activity in the Health Care Field Since 1968,* Carnegie–Mellon University, 1970.
14. *Report on the Interplay of Engineering with Biology and Medicine–Phase II,* Johns Hopkins University, 1970.
15. *Phase II Study, Interplay of Engineering with Biology and Medicine. Final Report,* University of Wisconsin, 1971.
16. *Phase II–A Study of the Effective Interplay of Engineering with Biology and Medicine in a Local Community,* Colleges of Engineering and Medicine, Ohio State University, and the Columbus Laboratories of the Battelle Memorial Institute, 1970.
17. *The Delivery System Perspective of Technology in Health Care,* University of Wisconsin, 1971.
18. *Final Report on a Pilot Study of the Delivery System Perspective of Engineering Technology in Health Care,* Bio-Medical Engineering Center, Ohio State University, 1971.

Appendix B Committee, Subcommittee, and Task Group Members (1967–1973)

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